REMARKS

At the outset, the undersigned wishes to thank Examiners Oh and Kishore for the courtesies extended during the February 25, 2003 interview. The substance of that interview was memorialized in Paper No. 9.

Claims 7 and 11 were amended to remove the word "an".

Claims 1, 15, and 16 were amended to, among other things, include an explicit recitation of the fact that the soft core of the present invention is a unitary soft core. This amendment is being made in view of Mehta. Support for the instant amendment can be found throughout the specification at, for example, Examples 1-4.

In addition, claims 1, 2, 3, 15, and 16 were amended to correct the term "drug" to "active agent." Support for the instant amendment can be found throughout the present application at, for example, paragraph 13 (p. 3, ln. 28) – paragraph 15 (p. 7, ln. 13).

Claim 8 was amended to recite that the hardness of the unitary soft core. Support for the instant amendment can be found throughout the present application at, for example, paragraph 23.

Claims 17-25 were added to the present application. Such claims are directed to, among other things, an oral dosage form having a unitary soft core of a specific hardness.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited

Obviousness Rejection

Claims 1-4 and 6-16 were rejected under 35 USC §103(a) as being unpatentable over Mehta (U.S. Patent No. 4,800,087). (Paper No. 8 at 2.)

Claim 5 was were rejected under 35 USC §103(a) as being unpatentable over Mehta in view of Lee (U.S. Pat. No. 6,060,078) ("Lee"). (*Id.*)

For the reasons set forth below the rejection, respectfully is traversed.

Mehta discloses a pharmaceutical composition having (1) a pharmaceutical core which is further comprised of a pharmaceutically active dose of a compound and, (2) a microencapsulating polymer which coats the pharmaceutical core and is capable of taste-making the active compound. (Abst.) Mehta was concerned with taste-masked pharmaceuticals and to taste-masked pharmaceuticals capable of being chewed without producing a bitter taste. (Col. 1, lns. 6-8.) Mehta discloses that the formulation includes a tablet which is further comprised of acetaminophen coated with a combination of polymers. (Col. 1, lns. 18-21.) According to Mehta, the acetaminophen chewable tablets do not exhibit the bitter and unpleasant taste normally associated with acetaminophen. (Col. 1, lns. 21-23.)

Mehta posits that, from a manufacturing cost standpoint, it is desirable to have chewable, taste-masked microcapsules that are large (0.25-1 mm in diameter), because larger microcapsules are easier to manufacture and package, and are less expensive to produce than are smaller microcapsules. (Col. 2, lns 18-22.) However, according to Mehta, an increase in size makes fracture during chewing and the release of drug from the microcapsule more likely to occur especially when there is an inadequate amount of plasticizer or other component included to provide elasticity. (Col. 2, lns. 23-27.) Mehta theorizes that a larger sized microcapsule requires greater elasticity to minimize the likelihood that a fracture will occur and active agent will be released. (Col. 2, lns. 27-30.) According to Mehta, there is a need in the art of pharmaceutical formulation to provide encapsulating coatings capable of being formulated into chewable microcapsules as large as about 1.5 mm., **that will not release drugs during chewing**. (Col. 2, lns. 30-34.) Metha listed several objects of the invention, which included chewable taste-masked formulation that can **provide immediate release of an active compound as soon as it reaches the stomach** and delayed release of the active agent in the upper intestinal tract (duodenum, jejunum, or ileum) or sustained release of the active agent. (Col. 2, lns. 56-64.)

According to Mehta, the taste-masked microcapsules include (1) a polymeric coating that may provide **chewable taste-masked characteristics** and (2) a pharmaceutical core of active ingredients. (Col. 4, lns. 4-8.) Mehta also discloses that once the pharmaceutical core has been coated it can then be encapsulated in a hard gelatin capsule, further coated with candy coating or pressed into tablet form or presented as a standard dosage form well known in the pharmaceutical formulation art. (Col. 9, lns. 35-39.) Metha's preferred uncoated acetaminophen particle size range is 150 to 300 microns. (Col. 10, lns. 45-46.)

Lee discloses a chewable tablet a core containing a medicament in a state of jelly or chewable base; and an outer layer of chewable base wrapping the core. (Col. 1, ln. 65 – col. 2,

ln. 3.) The medicament in the core was disclosed as being of bitter taste. (Col. 2, lns. 4-5.) Acetaminophen was disclosed as possibly being contained in the core. (Col. 2, lines 9-18.) According to Lee, the jelly base of the core, which contains the above medicament in a state of jelly, may be selected from the group consisting of pectin, sorbitol, maltitol, isomalt, liquid glucose, sugar, citric acid and a flavoring agent. (Col. 2, lns 29-32.) According to Lee, the chewable tablet provides taste mask effect to a bitter tasty medicament, which is contained in the medicament, and better chewing property and taste than the conventional tablets by means of an outer tasty chewable base. (Col. 3, lns. 54-57.)

In making the rejection, the Examiner asserted that "Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet." (Paper No. 8 at 2.) The Examiner contended that "the components of this dosage form comprise taste-masked microcapsules, which may then be prepared as chewable tablets." The Examiner also asserted that "the microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core." (Paper No. 8 at 3.) The Examiner also contended that "[a]cetaminophen and ibuprofen are listed among suitable drugs for use in the reference." The Examiner further asserted that "[d]iluents acceptable for use in the microcapsule core include gelatin." The Examiner also stated that "[i]n the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns and a rationale for such a limitation is given as well." The Examiner further stated that "[t]he reference also teaches that the coated pharmaceutical cores may then be encapsulated in hard gelatin capsule or further coated with candy." The Examiner opined that there is no criticality in the weight ratio of drug particles to the outershell. The Examiner further contended that "the inventions of the prior art perform their intended use, that is, the taste-masking and delivery of active substances, without explicitly possessing such characteristics" and the brittleness limitation of claim 6 is not critical. The Examiner acknowledged, however, that Mehta differs from the presently claimed invention because "Mehta does not teach the use of a pectin-based core."

To fill the acknowledged gap, the Examiner relied upon Lee as teaching "a chewable pharmaceutical dosage form consisting of a core containing an active ingredient and an outer layer. (Paper No. 8 at 3.) The Examiner asserted that "the core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin." The Examiner contended that gelatin may be used in either the core or outer layer to maintain hardness and hardness property of the dosage form. The Examiner further contended that the outer layer may take a

variety of forms, including hard candy. Additionally, the Examiner states that acetaminophen is listed as a possible active ingredient in the core.

The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art to combine the teachings of Mehta and Lee into the objects of the instant application. (Paper No. 8 at 3.) The Examiner concluded that both Mehta and Lee "teach a chewable dosage form, consisting of a brittle outer shell and a soft core, which masks the taste of the bitter active ingredients such as acetaminophen and ibuprofen; provides a pleasant mouth-feel; and is convenient to consume, thereby increasing the likelihood of patient compliance. (*Id.* at 4.)

At the outset the Examiner rejected claims 1-4 and 6-16 over Mehta and claim 5 over Mehta in view of Lee. However, it is not seen where the Examiner set forth any conclusion or reasoning for the rejection over Mehta alone. For this reason the rejection of claims 1-4 and 6-16 is improper and should be withdrawn.

Nonetheless, the claims have been amended to specifically recite, among other things, that the soft core is a unitary soft core. It is not seen where Mehta alone discloses such a core. In addition, the recited soft core contains, among other things, active agent particles having an average size of greater than about 50 μm. It is not seen where such a combination of unitary soft core and particle size of active agent particles is disclosed or suggested in Mehta alone or in Mehta in view of Lee. This is so because, among other things, the cited documents are concerned with taste masking. It is not seen where either document discloses the problem of texture masking. This problem is solved by the instantly claimed invention.

Obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, "cold hard facts." When a conclusion of obviousness is not based upon facts, it cannot stand.

For this reason, the rejection is improper, especially in view of the amendments to the claims set forth above.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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